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| 09/487,979 | 01/20/2000 | Boris Skurkovich | 0011-1U9 | 3797 |

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| EXAMINER |
|---|
| DECLOUX, AMY M |

| ART UNIT | PAPER NUMBER |
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| 1644 | 13 |

DATE MAILED: 06/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. 09/487,979 | Applicant(s) SKURKOVICH ET AL. | |
|---|---|---|---|
| | Examiner Amy M. DeCloux | Art Unit 1644 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *06 March 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *42,45,46 and 48-50* is/are pending in the application.

4a) Of the above claim(s) *45 and 48-50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *42 and 46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *15* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: [illegible]

## DETAILED ACTION

Applicant's amendment filed 3-6-02 (Paper No. 11) is acknowledged and has been entered.

Claims 42, 45-46 and 48-50 are pending.

Claims 45 and 48-50 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 7, filed 6-4-01.

Claims 42 and 46 are under consideration.

### *Priority*

Applicants contend that the instant application is entitled to priority to the parent document Application No. 08/025,408 because said parent document discloses a method of removing antigens from a patient with AIDS by passing fluid drawn from the patient through an immunosorbant which consists antibodies to at least one interferon and to TNF in the treatment of fluid from AIDS patients, and because said parent application discloses the basic knowledge that the removal of at least one interferon and TNF from the blood of a patient suffering from AIDS is beneficial. However, the examiner notes that a description of the priority material must meet the standards attributed to 112 first paragraph written description, in order for priority to be granted. Applicant is invited to point out the exact support for the instant claims' recitation of administering in a patient a combination of antibody to gamma interferon and an antibody to TNF-alpha in a method of treating AIDS in a patient.

### *Preliminary Amendment*

Regarding the non-entry of most of the amendments stated in Preliminary Amendment A filed 1-20-00, (Paper No.2), the amendments to pages 8-41 were not entered because the directions to amend specific words in specific line numbers did not match the specification. The examiner has attached Xeroxed copies of the pages of the specification in question. Applicant is invited to display how the requested amendments can be made given the disclosure of said pages.

***Information Disclosure Statement***

Applicant is thanked for the courtesy copy of the IDS references AF, AR, BT, BU, CD, CN and CT. .

The information disclosure statement filed 1-20-00 (Paper No. 1.5) fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered.

Specifically, Reference BU has no translation into English. Please see the attached copy of the 1449 form.

***Claim Rejections - 35 USC § 112***

In view of Applicant's amendments and remarks, the outstanding 112 second paragraph rejections have been withdrawn.

However the 112 first paragraph enablement rejection has been maintained in part, and the 112 first paragraph written description rejection has also been maintained, essentially for the reasons of record.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 42 and 46 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating Acquired Immunodeficiency Disease (AIDS) comprising administering a combination of an antibody to gamma interferon, (γIFN), an antibody to alpha interferon ( γIFN), and an antibody to tumor necrosis factor alpha, (TNFα), wherein said antibody is a monoclonal antibody, a polyclonal antibody, and biologically active fragments thereof, or allelic or species variants thereof, does not reasonably provide enablement for A) the broader recitation of a method of treating Acquired Immunodeficiency Disease comprising administering an antibody to αIFN, γIFN or TNFα wherein said antibody is any functional equivalent or any derivative thereof, as defined by the instant specification, nor for B) the broader recitation of a method wherein said antibody is directed against any TNF factor other than tumor necrosis factor alpha, (TNF ). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

### *Response to Arguments*

The amendment of claims 42 and 46 to recite TNF-alpha as opposed to any TNF overcomes part B of the outstanding 112 first paragraph enablement rejection.

Applicant traverses part A of said rejection regarding the lack of enablement for functional equivalents and derivatives of antibodies useful in the invention and disagree with the examiner's contention that that the scope of the terms "derivative" and "functional derivative" is too broad. Applicant also points out that said the terms are defined in the instant specification on page 21. In making the original rejection, the examiner acknowledged said disclosed definitions of terms "derivative" and "functional derivative" as indicated by a copy of part of said rejection below;

> "The instant specification provides enablement only for a method of treating Acquired Immunodeficiency Disease comprising administering antibody to gamma interferon wherein said antibody is a monoclonal antibody, a polyclonal antibody, and biologically active fragments thereof, or allelic or species variants thereof. However the specification fails to provide guidance as to how to make or use any functional equivalent or any derivative of the recited antibody, as defined by the instant specification. The instant specification discloses on page 21, that "functional equivalents" of an antibody include any molecule capable of specifically biding to the same antigenic determinant as the antibody, and as such encompasses a wide range of other non-antibody molecules, known and unknown. Additionally, the instant specification discloses on page 21 that "derivative" is intended to include both functional and chemical derivatives including analogs of a molecule and as such encompasses a wide range of non-antibody molecules, known and unknown. Because said claims recite no structural basis for the recited functional equivalent or derivative, it is therefore not clear how to make said equivalent or derivative, and the efficacy of said equivalent or derivative in the claimed method of treating Acquired Immunodeficiency Disease is unclear."

Applicant further contends that antibody technology is well known in the art and would dictate that a skilled artisan could develop quite easily antibodies having added moieties or antibody fragments which would bind the same antigens as the complete antibody, with which the examiner agrees. However it is noted, see above, that by the disclosed definitions of the terms "derivative" and "functional derivative", the instant claims encompasses a wide range of non-antibody molecules, known and unknown, and one of skill would not know how to make said molecules without further guidance and direction from the instant specification. Applicant further cites the Wands case that points to the fact that practitioners are prepared to screen negative hybridomas in order to find one that makes the desired antibody. The examiner notes that the application in the Wands case was limited to antibody molecules, unlike the present case wherein derivatives encompass non-antibody molecules.

MAINTAINED Claims 42 and 46 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

### *Response to Arguments*

As pointed out by applicant, the examiner acknowledges that claims 42 and 46 were intended to be rejected instead of claims 46 and 49, since claim 49 is non-elected and only two claims are under consideration. Applicant traverses the rejection on the grounds that one of skill in the art would know that in order for a functional equivalent to bind to the same antigenic

determinant the antibody binding site would have to be similar at least in sequence and/or structure to the antibodies taught in the invention. However it is noted that neither the sequence nor the structure of said antibodies has been described in the instant specification. Therefore, without a structural basis for the recited function, there is insufficient written description for derivatives or functional equivalents, except those that consist of antibody fragments with antigen binding sites with specificity for TNF or IFN gamma.

Applicant states that though the specification does not define a functional derivative, one skilled in the art would know that a functional derivative is one which performs the same or substantially similar functions as the antibodies of the present invention but which does not necessarily have the same form or structure. However, it is noted that in order to meet the requirements for written description, the invention must have a disclosed structural basis for the recited function of the claimed invention, or disclose a representative number of species to form a genus. It is noted that there is no disclosure of a specific non antibody derivative or functional derivative.

Though the claimed invention is directed to a method comprising antibodies, and not cDNA, the principle of the following still holds for said antibodies: a description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus, or of a recitation of structural features common to the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly&Co.*, 119F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). Thus, the specification has written support only for derivatives or

functional equivalents, except those that consist of antibody fragments with antigen binding sites with specificity for TNF or IFN gamma.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.)

Therefore, though applicant's arguments have been carefully considered, they are not deemed persuasive and the rejection is maintained, essentially for the reasons of record.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

MAINTAINED Claims 42 and 46 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Uehara et al. (Journal of Interferon Research 13, Supplement 1:PW6-9(Oct. 1993)), (IDS #CP), Skurkovich et al (U.S. Patent No. 4,824,432 (April 989) and Probert et al PNAS 92(24):11294-8 (Nov 1995).

### *Response to Arguments*

Applicants traverse the rejection on the grounds that two of the references do not qualify as prior art if applicant receives the contested priority date of the claimed parent document. However as discussed above and in the previous office action, applicant does not have support in the parent document for the recitation of the instant claims.

Applicant further traverses the rejection on the grounds that none of the articles contain the motivation to combine all the antibodies. However, the motivation to combine can arise from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combine for their common known purpose. Section MPEP 2144.07.

Therefore, though applicant's arguments have been carefully considered, they are not deemed persuasive and the rejection is maintained, essentially for the reasons of record.

### *Conclusion*

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy M. DeCloux whose telephone number is 703 306-5821. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703 308-3973. The fax phone numbers for the organization where this application or proceeding is assigned are 703 305-3014 for regular communications and 703 305-7401 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

Amy DeCloux, PhD
Patent Examiner, Group 1600
June 10, 2002

Patrick J. Nolan, PhD
Primary Patent Examiner, Group 1600